

March 29, 2001

Dr. Elizabeth Moran  
Manager, Olefins Panel  
American Chemistry Council  
1300 Wilson Blvd.  
Arlington, VA 22209

Dear Dr. Moran:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for the C5 Noncyclics category, dated November 6, 2000. I commend the ACC Olefins Panel for their commitment to the HPV Challenge Program and encourage you to take appropriate steps to make your submission a successful contribution.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Chemical RTK HPV Challenge Program website EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

The Panel presents a category approach for eleven substances and mixtures. EPA has reservations about the Panel's approach to a health effects category because of the absence of a well-defined mechanistic framework that would allow hazard characterization of such a diverse set of substances. As detailed in the attached Comments, EPA believes that the Panel needs to elaborate its approach in such areas as supporting the category with available data, metabolism discussions, and selection of test substances. The Panel also needs to explain the basis for the category for ecological and environmental fate endpoints. EPA disagrees with part of the Panel's plan to characterize ecological effects using modeled rather than experimental data to define the 100% isoprene stream. EPA also recommends neohexene as a representative test substance for ecological effects.

Consistent with our goal to maintain a quality standard for information obtained under this program, EPA prefers measured physicochemical property data to estimated data. For example, measured data are likely to be available for many of the chemicals in the C5 streams.

The sponsor needs to address deficiencies in 13 health robust summaries and the inadequacy of one summary. Summaries for available data cited in your submission (Table 4) may be needed where those data are used to support the category.

As with other submissions where the available data are either inadequate or insufficiently documented, this case will remain open until adequate documentation is in hand.

EPA will post this letter and the attached Comments on the Chemical RTK web site within the next few days. As noted in the comments, we ask that the Panel advise the Agency, within 90 days of the posting on the Chemical RTK website, of any modifications to its submission.

If you have any questions about EPA's response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-260-3470. Submit general questions about the HPV Challenge Program through the Chemical RTK web site comment button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at [tsc hotline@epa.gov](mailto:tsc hotline@epa.gov).

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

Oscar Hernandez, Director  
Risk Assessment Division

Attachment

cc: W. Sanders  
C. Auer  
M. E. Weber  
A. Abramson